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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,539	10/16/2003	Kevin T. Foley	5074A-000067	7710

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EXAMINER

KISH, JAMES M

ART UNIT	PAPER NUMBER
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3737

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/687,539	FOLEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	James Kish	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/3/04, 3/22/05, 9/19/06</u> .                                | 6) <input type="checkbox"/> Other: ____.                          |

## DETAILED ACTION

### *Claim Objections*

1. **Claim 77** is objected to because of the following informalities: Claim 77 requires a first member to have an additional first member, third member and fourth member. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claim 2** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 2 states that the first member includes a fastener operable to be fixed to a selected anatomical portion. There is no mention of a fastener anywhere else in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 5 and 38** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. **Claim 5** recites the limitation "said tracking element" in line 1. There is insufficient antecedent basis for this limitation in the claim.
5. **Claim 38** recites the limitation "wherein selecting a characteristic [of one of the members]" in line 1. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-18, 22-29, 33-44, 47-72 and 77** are rejected under 35 U.S.C. 102(b) as being anticipated by Foley et al. (US Patent No. 6,226,548).
7. **Claims 1-3:**

In an alternative interpretation of Claim 1, Foley describes a system that uses at least six separate pedicle screws 250 as shown in Figures 12 and 13. One of these is considered the first member. This first member is illustrated in Figure 7A as having a fastening portion 250 and an engageable portion (represented by the slots removed from the head of the screws). Second member is illustrated in Figure 8 as item 360. The third member is illustrated in Figure 8 and is represented by the

unlabeled fasteners that are protruding upward from the head of the first member 250 and simultaneously through second member 360. A localization element is found in Figure 7. Detection unit 110 of Figure 1 comprises an optical tracking unit along with processor 114. The localization element provides navigational information for all three members.

**8. Claims 1 and 4-18:**

Foley describes a system comprising a detection unit 110 of Figure 1 and subsequently, tracking elements for the system comprise an optical tracking system. Localization element is found in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first, second, and third members. Each member is illustrated in Figure 7A as having a fastening portion 250 and an engageable portion (represented by the slots removed from the head of the screws). The localization element provides navigational information for all three members and is illustrated in Figures 7 and 8. A fourth member 360 in Figure 9 engages first, second and third (not shown in Figure 9, see Figure 8) members.

With respect to **Claim 8**, see column 9, lines 51-58.

With respect to **Claim 9**, Figure 8 illustrates that when localization occurs, both first and second member will include a localization element extending therefrom.

With respect to **Claim 14**, see column 9, lines 38-43.

With respect to **Claim 15-16**, see column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

9. **Claims 22-29:**

Foley describes a system comprising a detection unit 110 of Figure 1, which comprises at least three separate detection device. The multiple detection devices create a sensor array and in turn represent the detection unit. The tracking elements for the system comprise an optical tracking system. Localization element is found in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first and second members and can be placed in the vertebrae prior to scanning (see column 9, lines 46-47). The localization element provides navigational information for both members and is illustrated in Figures 7 and 8. Figure 12 demonstrates the members after implantation. Figure 13 demonstrates the final position of the members after manipulation via probe 280, as shown in Figure 8.

With respect to **Claim 28-29**, see column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

10. **Claims 33-44 and 47-52:**

Foley describes a system comprising a detection unit 110 of Figure 1 and subsequently, tracking elements for the system comprise an optical tracking system. The tracking element is shown in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first, second, and fourth members. The tracking element provides navigational information for all three members and is illustrated in Figures 7 and 8. Figures 12 and 13 illustrate the determination of a selected alignment of the first, second and fourth members in relation to each other. A third member 360 in Figure 9 engages first, second and fourth (not shown in Figure 9, see Figure 8) members. During insertion, an optically tracked rod inserter can be utilized to guide the third member 360 through the slots of the first, second and fourth members (see column 10, lines 63-67). The rod geometry could also be visible and shown in real-time on monitor 106 as the operator is placing it in the other members (see column 11, lines 10-13). Also, the operator can use the computer to determine the required bending angles, or optimal position, of the rod (see column 11, lines 3-5).

With respect to **Claim 38**, the third member would be required to be flexible to allow for the computer to determine a required bend.

With respect to **Claims 43-44**, see column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

With respect to **Claim 51**, the positioning of third member does not require further imaging beyond those taken prior to operation due to the optical tracking system (see column 11, lines 1-13).

**11. Claims 53-66:**

Foley describes a system comprising a detection unit 110 of Figure 1 and subsequently, tracking elements for the system comprise an optical tracking system. The tracking element is shown in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first, second, and fourth members. The tracking element provides navigational information for all three members and is illustrated in Figures 7 and 8. Figures 12 and 13 illustrate the determination of a final orientation of the first, second and fourth members in relation to each other, excluding a third connecting member. The third member 360 in Figure 9 engages first, second and fourth (not shown in Figure 9) members. Figure 8 illustrates a final orientation including the third member. During insertion, an optically tracked rod inserter can be utilized to guide the third member 360 through the slots of the first, second and fourth members (see column 10, lines 63-67). The rod geometry could also be visible and shown in real-time on monitor 106 as the operator is placing it in the other members (see column 11, lines 10-13). Also, the operator can use the computer to determine the required bending angles, or optimal position, of the rod (see column 11, lines 3-5). Since bending is required, the third



member would need to be flexible to allow for the computer to determine a required bend.

With respect to **Claim 60**, see column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

**12. Claims 67-72:**

Foley describes a system comprising a detection unit 110 of Figure 1, which comprises at least three separate detection device. The tracking elements for the unit comprise an optical tracking system. The tracking element is found in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first and second members and can be placed in the vertebrae prior to scanning (see column 9, lines 46-47). The localization element provides navigational information for both members and is illustrated in Figures 7 and 8. Figure 12 demonstrates the members after implantation. Figure 13 demonstrates the final position of the members after manipulation via probe 280, as shown in Figure 8.

With respect to **Claim 71-72**, see column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

**13. Claims 67 and 77:**

In alternative interpretation of Claim 67, Foley describes a system comprising a detection unit 110 of Figure 1, which comprises at least three separate detection device. The tracking elements for the unit comprise an optical tracking system. The tracking element is found in Figure 7. Also included in the system is a processor 114. A first member is illustrated in Figures 2 and 2A-C. The first member comprises four members, or LEDs 122. These LEDs represent the first member's first, third and fourth members. At least six separate pedicle screws 250 are shown in Figures 12 and 13. Any one of these can be considered the second member and can be placed in the vertebrae prior to scanning (see column 9, lines 46-47). The tracking element provides navigational information for the second member and is illustrated in Figures 7 and 8. Figure 12 demonstrates the members after implantation. Figure 13 demonstrates the final position of the members after manipulation via probe 280, as shown in Figure 8.

**14. Claims 1, 5-12, 15-16, 19-24, 26, 28-33, 43-46, 49-52, 67-69 and 71-76 are** rejected under 35 U.S.C. 102(b) as being anticipated by Acker et al. (US Patent No. 6,332,089). Acker discloses a method of performing medical procedures using two or more probes. The procedure is performed using determined relative dispositions between the probes (see column 5, line 55 through column 6, line 8). The display for the invention need not show any image of the patient's tissue (column 12, lines 53-58).

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Plural probes can be coordinated with one another using information concerning their relative dispositions even without bringing the probes into close proximity to one another (see column 16, lines 46-65). See column 20, lines 9-64 for a written description of the display represented in Figure 18. Here there is shown icons relating to separate probe and a coordinate system, or atlas map, imposed behind the icons. If previously acquired image data is readily available and can be registered with the probe position data, the previously acquired image data can be displayed in registration with the indicia (see column 12, lines 54-58). Furthermore, column 2, line 57 through column 3, line 14 describes a probe function that can be implemented in an embodiment of Acker's system. The function provides for a probe to map the inner boundaries of the heart, thereby providing contour of a soft tissue.

### ***Conclusion***

Other related prior art:

Rogozinski	5,102,412
Yuan et al.	5,437,669
Melkent et al.	6,348,058
Mittelstadt	6,430,434

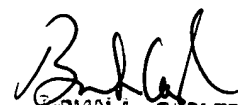
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Kish whose telephone number is 571-272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMK

  
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